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United States Senate

COMMITTEE ON HUMAN RESOURCES WASHINGTON, D.C. 20510

January 31, 1978

Dr. Arthur Kornberg Stanford Medical School Stanford, CA 94305

Dear Dr. Kornberg:

I want to thank you again for taking the time to share your views with me on January 19. I think the kind of exchange we had is essential to the formulation of science policy, and I hope we can continue our dialogue in the future.

I would also like to reiterate a point I made at our recent meeting. I have never questioned the intrinsic value of untargeted, investigator-initiated research, and I have always supported its generous funding at the National Science Foundation and at the National Institutes of Health. My commitment to investigator-initiated research is based on my firm belief, which I have expressed repeatedly in hearings and speeches, that this variety of inquiry promises to yield real benefits for the health and quality of life of our people. As I recall, you argued the case of untargeted research on the same pragmatic grounds, so on this matter we start from the same premises.

As you well know, however, it is much easier to espouse principles in the abstract than to implement them in practice. The promise of "basic" research is that it will yield knowledge which can be spun off in practical application. therefore, some portion of our research resources must be targeted on exploring the potential uses of new knowledge. Three questions arise. First, do we now have, or should we be designing some management system which will screen the results of research looking for potentially applicable findings? Secondly, what proportion of our resources should we devote to such a "transfer" system, as opposed to untargeted research, which is really the engine which runs the machine.

These are difficult questions, on which there is little empirical material. Men of good will should be able to differ in their answers without calling into question either their general support of science or their commitment to untargeted research.

In many ways your visit and your concentration on these issues comes at a particularly opportune time for the Subcommittee on Health and Scientific Research, which I chair. Over the last year the Subcommittee has had nine days of oversight hearings on issues in biomedical and behavioral research. During 1978 we plan to have six additional days. Obviously, this is a substantial commitment of Subcommittee time, but in my opinion, no more than the subject deserves.

During these hearings we have been exploring a series of questions, including the basic issue of setting an appropriate balance between investigator-initiated research and non-investigator-initiated research. It would be helpful for me and for the other members of the Subcommittee if you could help us wrestle with some of these problems. I will list below some questions which have come up, or were raised in my mind by your recommendations on January 19. We would appreciate any help you can give us with them.

- 1. Is "investigator-initiated research" an acceptable definition of "basic" research? Are not some forms of "contract" research also "basic"? I am told that the NIH, in struggling with this question, is coming to the conclusion that some contract research, especially when it is tied directly to an investigator-initiated project should really be classified as "basic".
- 2. If we accept "investigator-initiated" as synonymous with basic, what proportion of our research dollar should we invest in that category of inquiry? You suggest we return to the 1967 level of 61 percent? How do you justify choosing that particular baseline, as opposed to 30 percent, 50 percent, or 75 percent? What is so special about 1967?
- 3. When you recommend 61 percent as a target, do you mean 61 percent of each institute's outlay or 61 percent of NIH's total outlays without reference to particular institutes? And if you mean the latter, how is the basic research quota to be distributed among institutes? By the Director of NIH? By some outside group? What should the role of the Advisory Councils be under this revised system? Would they retain their role as quasi-legislative bodies which determine on a decentralized basis the appropriate distribution of dollars among research areas? What do we give up with such centralized resource allocation?

- 4. Would you want us to specify in legislation that some specific proportion of research dollars should go to investigator-initiated projects?
- 5. What proportion should go to center grants? To education and control efforts? To intramural as opposed to extramural projects?
- 6. Is the institute structure the best way to organize research expenditures?
- 7. Should all basic research dollars be spent by the Institute for General Medical Sciences? Is there such a thing as "targeted" basic research, and if not, how do we explain the often-voiced statement that the National Cancer Institute spends 50 percent of its money on "basic" research? Also, how do we reconcile the opinion of your group that NCI does "excellent" work with the fact that 64 percent of its money goes to "contract" work? If the work is "excellent", why change the current state of affairs?
- 8. Does the public have a role in deciding on the allocation of research dollars between categories of research expenditure? How and at what level?
- 9. Who should do clinical trials, how should they be organized, and how much should we spend on them?
- 10. Should we pay for clinical procedures before they have been thoroughly tested and reviewed? Wouldn't testing them constitute a way of preventing the indiscriminate application of half-way technologies? Or is such a plan too costly? If it were desirable, who should run it?
- 11. Does multi-disciplinary research get a fair hearing at NIH currently?
- 12. Do we have enough study sections? Do we have the right kinds of study sections?
- 13. Should there be a formal appeals system built into the peer-review process?
- 14. Would you recommend any changes in the internal structures, or of legal authorities for, any of the individual institutes at NIH?

Thank you again for visiting with us, and I look forward to any responses you may care to make to these inquiries.

Sincerely,

Edward M. Kennedy, Chairman Subcommittee on Health and Scientific Research